UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-CV-12257-PBS Sub-Category Case No. 1:08-CV-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators* *v.* *Baxter Hemoglobin Therapeutics and Baxter International Inc.*	Judge Patti B. Saris

BAXTER INTERNATIONAL INC.'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO DISMISS RELATORS' COMPLAINT[1]

In their Opposition to Baxter's Motion to Dismiss Relators' Complaint ("Opp."), Relators concede that Counts II, XII, XVI, XX, and XXI of the Complaint should be dismissed. Relators provide no basis for preserving the other counts that Baxter has moved to dismiss.

I. THERE IS NO SUCH THING AS "AN ENTIRELY NEW SPECIES OF AWP FRAUD."

Relators' counsel previously declared this matter to be an "AWP case."[2] Relators now claim that their case is about "an entirely new species of AWP fraud." Opp. at 2. Such semantics cannot help Relators escape the reality that "AWP fraud" was the subject of dozens of prior complaints and other public disclosures. Indeed, Sun admits that she was aware of these prior AWP suits, and that they formed a basis for the Complaint. Sun Decl.[3] ¶ 13. Relators are engaging in revisionist history.

[1] On September 23, 2009, Baxter filed a Motion for Discovery and an Extension of Time (Sun Sub-Docket No. 75). Baxter reserves the right to supplement its papers should the motion for discovery be granted.

[2] *See* Declaration of Ruchi Jain in Support of Baxter International Inc.'s Reply, Exhibit A (Transcript of June 22, 2009 Motion Hearing) at 4. Later exhibits to this Reply will simply be referred to as "Exhibit ___."

[3] The Sun and Hamilton Declarations referenced herein are attached to Relators' Opposition.

For example, Relators' Complaint seeks damages against Baxter "from at least 1998 to the present" because of Baxter's "reporting of false pricing statements regarding its products." *See* Complaint ¶¶ 108, 117, 127, 137, 147, 157, 167, 178, 189, 200, 210, 220, 229, 238, 247. But Relators now claim that their "new species of AWP fraud" "*could not even have existed before the reporting mechanism changed in 2000*," and therefore that "prior complaints and articles discussing other forms of AWP fraud" are irrelevant. Opp. at 1 (emphasis added). If the "new" type of AWP fraud first arose in 2000, then Relators cannot seek damages going back to 1998. Relators' inconsistent arguments further expose their jurisdictional bind.

Moreover, Relators admit that Baxter's settlements with Texas and Nevada are duplicative of the allegations in their Complaint and that the Counts related to these two states should be dismissed. Opp. at 17-18. In fact, Relators say that the Nevada agreement "explicitly details similar conduct as discussed in Relators' Complaint. The agreement purports to release 'claims regarding any drug price published by any commercial price reporting service, or provided by any Released Party to any such commercial price reporting service.'" Opp. at 18. Relators cannot square this admission with their contention that the Complaint relates to an "entirely new species of AWP fraud," not addressed in any prior case.

II. THE SCHEMES ALLEGED BY THE RELATORS WERE PUBLICLY DISCLOSED PRIOR TO RELATORS' COMPLAINT.

A. Best Price and Volume Committed Contract Fraud

Baxter has cited paragraphs in pre-existing complaints that mirror Relators' Best Price and Volume Committed Contract ("VCC") allegations. Baxter's Memorandum in Support of Motion to Dismiss ("Memorandum") at 5-6.[4] There is nothing new in Relators' Complaint

[4] Another complaint asserting Best Price violations includes Exhibit B (Complaint in *Digel v. Abbott Labs., Inc., et al.*, Case No. CT-007177-02 (Tenn. Cir. Ct., 30th Jud. Dist., Dec. 18, 2002)) ¶¶ 14, 66-69. Paragraph 58 also discusses volume discounts and quotes a Baxter document about such discounts.

regarding these allegations. Relators' own statements thus demonstrate that the VCC allegations were disclosed in prior litigation. *See* Sun Decl. ¶ 13 (one reason Sun believed Baxter's VCCs were "illegal" was because of her "awareness of AWP litigation.").

B. AWP Fraud

While Relators attempt to re-label their AWP allegations, the fact remains that AWP fraud was disclosed long before Relators' 2005 Complaint. In the end, at issue is Baxter's alleged attempt to keep published AWPs artificially high. Whether Baxter did this by reporting an "inflated" AWP to the publications or, according to Relators' construct, by not reporting a WAC and instead supplying a "list price" that Baxter knew would be marked up to an "inflated" AWP,[5] does not matter. The primary allegation of AWP fraud is the same – that government programs basing reimbursement on AWP overpaid because Baxter's AWP was too high.

1. Disclosures in Prior Complaints

Because of this Court's prior AWP knowledge, Baxter did not cite each and every paragraph of each and every prior complaint that parallels the Relators' AWP allegations. Our citations to similar allegations in the MDL Master Consolidated Complaint ("MCC") and Nevada complaint, Memorandum at 5, are more than enough to demonstrate public disclosure. *United States ex rel. West v. Ortho-McNeil Pharm., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.*), 538 F. Supp. 2d 367, 377, 380-82 (D. Mass. 2008). However, other cases have also alleged misreporting of AWP and WAC to First DataBank and other publishers.[6]

[5] As described *infra* at 7, this allegation is not based on original source information, but on conjecture on the part of Hamilton.

[6] *See, e.g.*, Exhibit C (Complaint in *People of the State of Illinois v. Abbott Labs., et al.*, Case No. 05 CH 02474 (Cir. Ct. Cook Cty. Feb. 7, 2005)) ¶¶ 2, 45-56, 66-68 (¶¶ 46, 56, and 66-68 specifically refer to the misreporting of WAC by manufacturers); Exhibit D (First Amended Complaint in *State of Wisconsin v. Amgen Inc.*, Case No. 04-CV-1709 (Cir. Ct. Wisc. Nov. 1, 2004), ¶¶ 1, 33-56 (¶¶ 34, 44, 48, and 54-56 specifically refer to the misreporting of WAC); Exhibit E (First Amended Complaint in *Nevada v. Abbott Labs., Inc., et al.*, Case No. 02-00260, Dept. No. 8 (2d Jud. Dist. Ct., County of Washoe, Oct. 31, 2003)) ¶¶ 181-194 (¶¶ 186 and 189 specifically mention manipulation of WACs and quote a Baxter document on this point).

Even if Relators have provided a few new details about Baxter's alleged AWP fraud, they cannot go forward. Where only *some* of the allegations have been publicly disclosed, the disclosure still bars the entire *qui tam* suit. *See United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 552 (10th Cir. 1992) ("An FCA *qui tam* action even partly based upon publicly disclosed allegations or transactions is nonetheless 'based upon' such allegations or transactions."); *see also West*, 538 F. Supp. 2d at 377 (under the majority view adopted by the Court, a *qui tam* suit is based upon a public disclosure when its allegations are "similar to, supported by, or 'the same as' those that have been publicly disclosed.'") (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992)); *United States ex rel. Rosales v. San Francisco Hous. Auth.*, 173 F. Supp. 2d 987, 995-97 (rejecting argument that to be barred FCA allegations must "repeat" or "mirror" public disclosures and finding that, although the precise manner of implementing the alleged fraud had changed over time, the allegations could not "be reanimated simply by complaining that the defendants performed the same fraudulent acts in succeeding years."); *cf. United States ex rel. Wang v. FMC Corp.*, 975 F.2d 1412, 1418 (2d Cir. 1992) ("the Act bars suits based on publicly disclosed 'allegations or transactions,' not information . . . . An allegation can be made public, even if its proof remains hidden.").

2. Disclosures in News Media

First, the contention that "none of the [media] reports cited ever mention anything remotely like resembling (*sic*) Baxter's scheme," Opp. at 5, is simply wrong. *See* Memorandum at 8-9. And, the fact that Marketing Research Bureau ("MRB") reports may be expensive and have limited circulation is not enough to make these reports non-public. Relators argue that the MRB reports are "not available to 'any stranger to the fraud'" who might be interested. Opp. at 5. But the reports were sufficiently available such that Relators themselves could cite a MRB report in their Complaint. Complaint ¶ 29.

III. HAMILTON AND SUN ARE NOT ORIGINAL SOURCES.

A. Sun

By Sun's own admission, she was primarily responsible for a single product, Advate, while at Baxter. Opp. at 9; *see also* Sun Decl. ¶ 5. Sun alleges that she "also did pricing for other Baxter products as well," Sun Decl. ¶ 5, but provides no further specifics. This lack of specificity – in the face of a motion to dismiss – proves her lack of direct and independent knowledge.[7]

Sun's ability to add details about Advate, a third generation hemophilia factor, does not give her original source status. Other hemophilia therapies referenced in the Complaint include Bebulin, Feiba, Hemofil M, Proplex T, and Recombinate. *See* Memorandum at 7 n. 9 and 17 n. 14. Of these, all but Advate and Feiba were named in the MCC. MDL Docket No. 148, ¶ 71. The same drugs also were included in the Nevada complaint.[8] In short, Sun has not added anything significant to the previously alleged Baxter AWP schemes.

Even if AWP claims about Advate are deemed not to have been included in prior complaints, Sun cannot pursue them. Sun worked for Baxter from June 24, 2002 through July 22, 2003. Complaint ¶ 7. At most, Sun's actual knowledge covers this thirteen-month period. *See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 109 (D. Mass. 2008), *aff'd in part, rev'd in part*, No. 08-1409, 2009 WL 2450716 (1st Cir. Aug. 12, 2009) (relator's direct knowledge of his employer's activities "only extends to the time he was employed by the company"); *cf. Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 475 (2007) (relator's prediction of what would occur after he left a company's employ is not knowledge). Advate was not even approved by the FDA for sale, and Baxter did not send any information

[7] Sun's conclusion that Baxter's VCCs were illegal based on her "awareness of AWP litigation," Sun Decl. ¶ 13, is an admission that she lacks direct and firsthand knowledge.

[8] *See* Exhibit E, Nevada First Amended Complaint, ¶ 181.

about Advate to the publications, until July 28, 2003, *after* Sun left Baxter. Opp. at 1; Exhibit F, Guiheen Decl. ¶ 9. Baxter did not begin to sell Advate until August 20, 2003, two months after Sun left Baxter's employ. *See* Exhibit F, Guiheen Decl. ¶ 9. Therefore, no false claim could have been submitted regarding reimbursement for Advate of which Sun would have had any direct or firsthand knowledge.

B. Hamilton

Hamilton alleges that he had several meetings with Baxter executives in which "pricing" was discussed. Hamilton Decl. ¶¶ 2, 4-7. Hamilton claims that one of these meetings included a discussion about the pricing of Advate and that, a few months later, Baxter changed its price to "within a penny" of what Hamilton had "recommended." *Id*. ¶ 6. However, Hamilton has no actual knowledge of *how* or *why* Baxter decided to set the price for Advate. The implication that Baxter acted pursuant to a "recommendation" from Hamilton is little more than arrogance and speculation. Hamilton does not connect any of the other alleged interactions he had with Baxter executives in the course of his roles as either a customer or competitor with any allegation in the Complaint, stating only that these "meetings" included discussions about "pricing." *See id*. ¶¶ 2, 4, 5, 7.

The implication that Hamilton's "pricing" discussions with Baxter somehow relate to the allegations in the Complaint is patently false. While Relators clearly would like the Court to have the contrary impression, the carefully worded statements in Hamilton's declaration, informed by additional details surrounding the "meetings," demonstrate otherwise. The attached declarations of Larry Guiheen and Peter O'Malley confirm they met with Hamilton a few times during the period 2003 to 2006, when Hamilton was a representative for Baxter customers Express Scripts and CuraScript. Exhibit F, Guiheen Decl. ¶ 5; Exhibit G, O'Malley Decl. ¶ 5. Several of these "meetings" were little more than encounters at large national hemophilia

conventions. *See* Hamilton Decl. ¶ 4. The "pricing" that was discussed concerned "only the prices that Express Scripts and CuraScript would pay for Baxter therapies." Exhibit F, Guiheen Decl. ¶ 6; Exhibit G, O'Malley Decl. ¶ 6. At no time were AWP, WAC, or Best Prices ever discussed with Hamilton. Exhibit F, Guiheen Decl. ¶ 10; Exhibit G, O'Malley Decl. ¶ 9. Hamilton was not privy to any Baxter pricing decisions, and he did not have any influence on the pricing for Advate. Exhibit F, Guiheen Decl. ¶¶ 7-8, 10-11; Exhibit G, O'Malley Decl. ¶¶ 7-8, 10. Hamilton hopes to imply firsthand knowledge, but the fact remains that all of his information is based upon conjecture and independent research of publicly available information. He is not an original source.

Nor is Hamilton an original source with respect to Baxter's price reporting to First DataBank. Hamilton cites First Databank's Kay Morgan as a source of his knowledge about Baxter. Hamilton Decl. ¶¶ 8-10. Morgan's hearsay description of what Baxter did or did not do is clearly not firsthand knowledge of the alleged fraud. *See United States ex rel. Barth v. Ridgedale Elec. Inc.*, 44 F.3d 699, 703 (8th Cir. 1995) ("a person who obtains secondhand information from an individual who has direct knowledge of the alleged fraud does not himself possess direct knowledge and therefore is not an original source under the Act."); *accord United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 96 (D. Mass. 2001). Moreover, Hamilton's declaration speaks only of what he speculated to be the reason for Baxter's alleged refusal to disclose WACs to FDB:

> Morgan asked me what I thought Baxter was trying to accomplish by this [refusal to provide WAC information]. I told her that *I thought* Baxter's goal was to establish an AWP [that] was attractive to the distributors, but to still be able to deny to the hemophilia community that it was Baxter's fault for the high AWP, and to blame FDB.

Hamilton Decl. ¶ 10 (emphasis added). Hamilton is simply describing what he "thought." He has no firsthand knowledge of the real reasons for Baxter's actions. Baxter's alleged refusal to

disclose WACs to FDB constitutes Relators' "new species of AWP fraud," Opp. at 1, yet this information is based solely upon Hamilton's speculation.

IV. RELATORS' STATE CLAIMS MUST BE DISMISSED.

Relators have dropped claims for those states where there is no private right of action to pursue false claims (Utah and Arkansas). Opp. at 17. They also have conceded that the Texas and Nevada settlements preclude any claims on behalf of those states. *Id*. Relators came to a different conclusion with respect to Baxter's settlement agreements in California, Illinois, and Hawaii, *id*. at 18-20, although these are indistinguishable from the former, for the reasons set forth in our Memorandum at 20-21.

Regardless, the Court clearly lacks jurisdiction over *any* of the remaining state law claims. The only government official Relators' counsel claims to have spoken with prior to filing the Complaint is Michael Theis, an Assistant United States Attorney in the District of Colorado. Opp. at 11 and Decl. of Mark Kleiman. Relators' counsel make no assertion that they contacted any state personnel. Thus, they implicitly acknowledge that they did not make any pre-complaint disclosures to the states of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, New Mexico, Tennessee, Virginia, or the District of Columbia (the states remaining in the case). For this reason alone, all of the remaining state claims must be dismissed for lack of jurisdiction, as pre-filing disclosure is a requirement under each state's pertinent false claims act statute. *See* Memorandum at 18. The state law claims also should be dismissed for the additional reasons set forth in our Memorandum at 18-21.

V. RELATORS' COMPLAINT IS INSUFFICIENT UNDER FED. R. CIV. P. 9(B).

Relators assert that if Rule 9(b) is read in conjunction with Rule 8(a), they are not required to set forth "evidence" in their Complaint. Opp. at 13. However, because Relators need

not produce all of their evidence now does not mean that they can ignore the minimum standard of establishing jurisdiction under the False Claims Act.

Relators concede they have provided detail about the pricing of only two Baxter drugs – Recombinate and Advate. *See* Opp. at 15 ("[The Complaint] details how Baxter misreported the price of Recombinate and Advate."). Relators make exactly one mention in their 74-page Complaint of each of the ten other drugs allegedly at issue, in an introductory paragraph stating that this case applied to those drugs. *See* Memorandum at 17 (citing Complaint ¶ 20). This does not even rise to the level of notice pleading under Rule 8(a); it is certainly not sufficient for Rule 9(b). These are the very same sorts of "labels and conclusions" the Supreme Court rejected in *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009); *see* Opp. at 13.

VI. RELATORS SHOULD NOT BE GIVEN LEAVE TO AMEND TO CORRECT THEIR PLEADING DEFICIENCIES.

Relators' request for leave to amend to correct their pleading deficiencies related to Rule 9(b) and the Stark Act should be denied. Under Rule 15(a), courts may freely grant leave to amend "when justice so requires." However, courts can deny a motion to amend for reasons including "undue delay, bad faith or dilatory motive . . . undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Hayes v. New Eng. Millwork Distribs., Inc.*, 602 F.2d 15, 19-20 (1st Cir. 1979). It is apparent from Relators' declarations that they can offer no further information to address the Rule 9(b) deficiencies. Their failure to plead claims with the requisite particularity is inextricably linked to the fact that Relators are not original sources. They have alleged no new facts or arguments to suggest that an amendment would strengthen their case. *See Palmer v. Champion Mortg.*, 465 F.3d 24, 30-31 (1st Cir. 2006) (upholding district court's rejection of request to amend because plaintiff made request more than nine months after initially amending complaint and was aware of the factual predicate on which her proposed new theory rested

before she brought suit). Leave to amend in this instance would be a futile exercise and would result in undue delay and prejudice to Baxter.

Admitting that they did not plead valid Stark Act claims, Relators now seek to add federal and state "cognate" Anti-Kickback Act claims. Opp. at 20. Plaintiffs should not be rewarded for their careless research and draftsmanship. This Court previously denied leave to amend to add kickback claims to a complaint because the claims, though "viable," were part of a "sweeping new theory by Relator more than five years after commencing this action [which] constitutes undue delay and would cause undue prejudice to Defendant." *United States ex rel. Franklin v. Pfizer, Inc.*, No. Civ.A. 96-11651-PBS, 2002 WL 32128635, at *1 (D. Mass. Feb. 6, 2002). Relators here initially alleged that Baxter violated the Stark Act by providing volume-based discounts to institutional providers; they now have shifted to making supposed kickback claims based on the accusation that Baxter concealed discounts from CMS and underpaid rebates to the states. Opp. at 20. Relators' belated request for leave to amend should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I, Ruchi Jain, an attorney, electronically filed the foregoing MEMORANDUM IN SUPPORT OF BAXTER INTERNATIONAL INC.'S MOTION TO DISMISS RELATORS' COMPLAINT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on September 30, 2009. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties. In addition, the individuals listed below were served a courtesy copy via U.S. Mail.

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